

**REMARKS**

**Rejection under 35 U.S.C. §112**

Claims 1 and 5 were rejected under 35 U.S.C. 112, second paragraph as being indefinite. The Examiner questions whether “consisting of at least 90% identity to....” means that the identity is equal to 90% or more than 90% (at least). It is respectfully submitted that “consisting of at least 90% identity to...” clearly means that the claimed sequence has ***at least*** 90% identity to the reference sequence of SEQ ID NO:1.

Upon this explanation indefiniteness rejection to claim 5 is believed to be withdrawn.

**Rejections Over Prior Art**

Claims 1, 3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coleman et al, WO97/24441, and further in view of Ushio et al (*J. Immunol.* (1996) 156:4274-79). The Examiner says, *inter alia*, that

*Coleman discloses a human IGIF-2 polypeptide, which amino acid sequence of SEQ ID NO:2 has 193 residues, and the amino acids 36-193 is 100% identical to the present SEQ ID NO:1 (157 amino acids). Additionally, Coleman teaches that said polypeptide can be used for treating diseases/conditions including, among others, Crohn's disease or other inflammatory bowel diseases (the paragraph bridging pages 35 and 36). Coleman does not teach a polypeptide consisting of 90% identity to SEQ ID NO:1 (157 amino acids).*

Further the Examiner says out that Ushio teaches that the N-terminal amino acid sequence for the natural IGIF starts at the 37<sup>th</sup> residue, thus, Ushio's natural IGIF is 100% identical to the present SEQ ID NO:1. The Examiner also says that

*...Ushio teaches that the recombinant precursor IGIG (193 amino acids) shows little biological activity (page 4276, the last paragraph of the right column). It would have been obvious to the person of ordinary skill in the art at the time the invention was made to use the active (natural) form of IFIG (157 amino acids) taught by Ushio in a method of treatment of diseases such as IBD as indicated by Coleman because Ushio teaches that the precursor of IGIF (193*

Serial No.: 10/518,333  
Group Art Unit No.: 1646

*amino acids) shows little biologic activity. The person of ordinary skill in the art would have been motivated to use the natural form of IGIF for disease treatment because it is biologically active, as indicated by Ushio, and reasonably would have expected success because Ushio has demonstrated that the natural form of IGIF exhibited the biologic functions such as induction of IFN- $\gamma$  production.*

It is respectfully submitted that Examiner's rejection is critically flawed. First, as Examiner points out Coleman says that protein of sequence 193 amino acid (which includes leader sequence) can be used for treating Crohn's disease or other inflammatory bowel disease. Coleman does not teach that protein of amino acids 37-193 is active against Crohn's or inflammatory bowel disease. If one extends the Examiner's argument, what Coleman taught is contradicted by Ushio, because according to the Examiner, Ushio says that recombinant precursor IGIF (193 amino acids) shows "little biological activity." For the record Ushio did not say on page 4276 that IGIF (193 amino acids) shows little biological activity. All it said was "the recombinant precursor IGIF showed little effect on Con A-stimulated PBMC in the production of IFN-gamma," which has nothing to do with Crohn's disease or inflammatory bowel disease.

In view of the above remarks and amendments, Applicants believe the application is in condition for allowance. Reconsideration of this application is requested. Should the Examiner have any questions or wish to discuss any aspect of this case, the Examiner is encouraged to call the undersigned agent at the number below.

Respectfully submitted,



William T. Han  
Attorney for Applicant  
Registration No. 34,344

GLAXOSMITHKLINE  
Corporate Intellectual Property - UW2220  
P.O. Box 1539  
King of Prussia, PA 19406-0939  
Phone (610) 270-5263  
Facsimile (610) 270-5090  
N:\HAN\APPS\TB Cases\TB00005\Amendment2.doc